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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,723	01/29/2001	Peter G. Webb	10010016-1	1312

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AGILENT TECHNOLOGIES  
Legal Department, 51U-PD  
Intellectual Property Administration  
P.O. Box 58043  
Santa Clara, CA 95052-8043

[REDACTED] EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	[REDACTED]

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/772,723	WEBB, PETER G.
Examiner	Art Unit	
Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 October 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 15-44 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-44 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Applicant's election with traverse of Group I (claims 1-14) and Specie B (plural array fabrication) in Paper No. 7, filed 10/10/02, is acknowledged.

The traversal is on the grounds that Group II should not be separated from Group I.

The applicant's request to withdraw the restriction between Groups I and II was found unpersuasive because of the following reasons:

As stated in the Restriction Paper No. 6, mailed 9/5/02, Group I requires shipping of the arrays while Group II does not require any shipping of commercial type array fabrication. Furthermore, the apparatus of Group II can be used to fabricate an addressable array. Because the apparatus is computer operated, it can be used for different purposes, such as printing a bar code, printing a shipping address, or even printing a string of text on any surface such as paper. Therefore, Group II is considered a patentably distinct invention.

The requirements are still deemed proper and are therefore made FINAL.

Claims herein under examination are claims 1-14.

*Claim Objections*

Claim 1 is objected to because of the following informality: the presence of two "(d)" steps. Applicant is requested to edit the "(d)" on line 10 to an "(e)". Appropriate correction is required.

Claim 10 is objected to because of the following informality: the claim is identical to claim 3. If applicant chooses to have claim 10 dependent from claim 8, then the “2” should be replaced with an “8.” Appropriate correction is required.

***Claims Rejected Under U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph. While being enabling for generating an addressable array of biopolymers on a substrate via ink jet head fabrication method driven by a software (page 13, lines 21-33; page 14, lines 25-33; and page 15, lines 1-7), identification of the arrays via generation of bar code (page 9, line 14 and page 15, lines 8-12), and data transfer via network (page 13, lines 6-14), the specification does not reasonably provide enablement for generating an addressable array via *any* fabrication method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or

direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claim 1, and its dependent claims 2-7 therefrom, are directed to a method of generating an addressable array of biopolymers on a substrate by obtaining biopolymers, depositing the biopolymers on the substrate, saving an identity map in a memory associated with a map identifier, applying the map identifier to the substrate or housing carrying the substrate, and shipping the array to a remote location. However, claim 1 does not adequately limit the nature of the fabrication method.

Claims 8-14 are directed to a method of generating addressable arrays of biopolymers on multiple substrates, but at a central fabrication station.

It would require undue experimentation for a person having ordinary skill in the art to practice the claimed invention because the sequential steps comprising the method of generating an addressable array employ materials and reagents whose chemical and physical attributes directly affect the outcome of the claimed processes, and Applicant has not shown how independent variation of one or more of the components in the scheme would affect the outcome of the claimed method. Without a more explicit definition in the claims of the nature of the fabrication method, the skilled artisan would not be able to practice the claimed invention without undue experimentation. The

method of fabrication encompasses any method, i.e., spotting via capillary or pipetting, in situ, etc. However, each different fabrication method requires a different set of conditions. For example, photolithography technology requires a unit of biopolymer linked to a photo-removable blocker. It also may require a set hybridization/washing conditions, coupled with different “making.” Capillary spotting technique, on the other hand, requires different set of conditions for spotting, such as linking chemistry of the substrate to the biopolymers, the optimal concentration and amount of biopolymers spotted, etc.

The amount of direction presented in the specification is limited to a narrow range of conditions using defined parameters that are only meaningful when taken together. Applicant discloses a method of fabrication employing a specific apparatus, but the breadth of the claims is such that no limitation is placed on this component. The nature of the invention relates to complex and empirical art of an addressable array fabrication. The state of the prior art is such that a multitude of fabrication methods are known, but the methods are uniquely tailored to the specific fabrication technology. The relative skill in the art is commonly recognized as being quite high but the complexities associated with fabrication methods are also quite high for the reasons set forth in the previous paragraph. The breadth of the claims is such that they encompass virtually any fabrication method. However, the amount of guidance presented in the specification would not enable the skilled artisan to practice the claimed processes for the fabrication of an addressable array in a manner reasonably correlated with the scope of the claims.

Therefore, the experimentation required for a person having ordinary skill in the art would be undue.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 and 8 recite the word “regions.” It is unclear what is meant by “regions” and their specific characteristics, such as size, shape, overlapping, non-overlapping, etc. Clarification of the metes and bounds of “regions” via clearer claim wording is required. Claims 2-7 and 9-14 are also rejected due to their dependency from claims 1 and 8.

Claims 5, 6, 12, and 13 recite the phrase “portable storage medium.” It is unclear exactly what is meant by this phrase as it is broadly defined and could encompass any object containing another object that is moved from one location to another, such as a box or a computer disk. Clarification of the metes and bounds of this phrase via clearer claim wording is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. (1998), in view of Gamble et al. (1999), Coles (1994), Shakib et al. (1998), Brown et al. (1998), and Balaban et al. (2001).

Cozzette et al. teach a method of generating an addressable array on a substrate, more specifically, fabrication of an array by capillary spotting technique via an automated system which is able to microdispense precise and programmable amounts of biopolymers used in the biosensors (or generally, “substrates”) of interest (col. 12, lines 66-67 and col. 57, lines 36-40). Cozzette et al. teach the biopolymers used in this technique include DNA (col. 18, lines 46-54). Cozzette et al. teach the use of an apparatus operated by customized software to deposit biopolymers into different regions in positions which may be reproducible within  $\pm$  13 microns or better in either x or y directions.” (col. 57, lines 49-53). Cozzette et al. also make reference to a published Japanese Patent Application No. 59-24244, where an ink jet nozzle technology is employed for deposition of enzymes on to a substrate (col. 7, lines 47-54).

Cozzette et al. do not teach saving an identity map in a memory, the generation of an identifier and its application on to the substrate or a housing of the array, or the shipment of the array. Cozzette et al. do not teach the method of generating the array at a central fabrication station and making associated map identifiers that are communicated to physically remote stations and from the central fabrication station. Furthermore, Cozzette et al. do not teach the communication of the information via network (i.e., LAN

(Local Area Network), WAN (Wide Area Network), e-mail, etc.) or computer readable storage media. Cozzette et al. do not specifically teach the fabrication of an addressable array employing the ink jet nozzle to deposit the biopolymers.

Gamble et al. (1998) teach the use of a pulse jetting device to deposit nucleic acids on arrays (abstract).

Brown et al. (1998) teach the distribution of DNA reagents via microarrays to researchers (col. 14, lines 36-42).

Balaban et al. (2001) teach that portable storage media may be used to carry information between computers (col. 6, lines 16-18).

Coles teaches the fabrication of an identifier, a computer-readable bar code, on the surface of a silicon substrate to produce a location image of DNA specimen (abstract). Coles teaches the “etching” of computer-readable bar codes via photolithography (col. 3, lines 48-50) which permits STM (Scanning Tunneling Microscope) to scan across the substrate and then return to the originally imaged section of the grid for a repeat image, whenever desired (col. 2, lines 60-63). Thus, Coles demonstrates the fabrication of identifiers (bar codes) and the ability to retrieve information associated with them.

Shakib et al. teach an asynchronous store and forward data replication system and the method utilizing existing computer networks and/or network control software as a transport agent to deliver the communication messages (abstract). Shakib et al. teach a system and method which can generate information from a remote station (i.e., creation of new data, modification of existing data, or deletion of existing data) (col. 3, lines 20-

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28), and communicate to another remote station over foreign networks such as the Internet or other Wide Area Network (WAN) (col. 5, lines 28-32). Shakib et al. teach the assignment of all data sets and individual objects which make up the data sets with unique IDs, allowing them to be tracked throughout the network (col. 4, lines 39-46). Furthermore, Shakib et al. teach the access of privileged information via use of IDs of the data set (col. 4, lines 50-57).

It would have obvious to a person of ordinary skill in the art at the time the invention was made to use the software driven, automated array fabrication system, as taught by Cozzette et al. and incorporate the teachings of Gamble et al., Coles, and Shakib et al. One of ordinary skill in the art would have been motivated to combine the teachings of the above references for the following reasons:

Cozzette et al. teach an automated array fabrication system driven by a software which gives a specific set of directions (i.e., x and y coordinates of where the fabrication should take place, amount of biopolymers dispensed, the distance between the fabricated spot, etc.). Cozzette et al. employ a syringe as the dispensation unit (capillary technique), while Gamble et al. teach the fabrication method using a pulse jetting device. Both are functional equivalents. Both employ a device, either syringe or capillary to dispense specific amounts of liquid through an orifice where the depositing movements, (i.e.. x and y coordinates) are controlled by a set of instructions from a software. It is well known in the art of array fabrication, to identify an array type by fabricating the identity on the substrate with control oligos (any microarrays of Affymetrix). It is also well known in the art to identify any physical object by “barcoding” it (Federal Express,

United Parcel Service). Coles teaches the fabrication of computer-readable bar codes on an array's substrate to retrieve information. It would have been obvious to incorporate the teachings of Coles to fabricate a bar code or any identifier on the array's substrate to retrieve the information regarding the array (such as the identity of the array, the layout of the array). Shakib et al. also teach the ability of data or data sets (i.e.. information) transfer from a remote station, such to another remote station and the ability to generate unique identifiers to track down and access the data or data sets. The ability to communicate, access, or exchange data through network, such as e-mail, WAN, LAN, the Internet, etc., would be advantageous since it would allow communication of any information (even an array design) between physically separate individuals, companies, or entities, quickly. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Shakib et al. to the above teachings to expedite the data transfer/access, or more specifically, array designs and any pertaining information thereof, to the array generation scheme.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success by combining the above teachings to fabricate an addressable array where a unique identifier is either fabricated on the substrate of the array or labeled on the array housing and then distributing the arrays and portable storage media to researchers so that experiments could be conducted as researchers would have the portable storage media to correctly identify locations of their test compounds. Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in combining the data access/transfer teachings of Shakib et al. to communicate

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an array design made at one location to another remote location, where an addressable array employing the above combined technology is fabricated. Therefore, the claims are obvious over the cited references.

***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 11, 2002

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER